

to all authorities and the Joint Committee described in subpart C of this part;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that a CAB may no longer be equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

§26.48 Harmonization.

During both the transitional and operational phases of this subpart, both parties intend to continue to participate in the activities of the Global Harmonization Task Force (GHTF) and utilize the results of those activities to the extent possible. Such participation involves developing and reviewing documents developed by the GHTF and jointly determining whether they are applicable to the implementation of this subpart.

§26.49 Regulatory cooperation.

(a) The parties and authorities shall inform and consult with one another, as permitted by law, of proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to Appendix A of this subpart.

§26.50 Alert system and exchange of postmarket vigilance reports.

(a) An alert system will be set up during the transition period and maintained thereafter by which the parties will notify each other when there is an immediate danger to public health. Elements of such a system will be described in an Appendix F of this subpart. As part of that system, each party shall notify the other party of any confirmed problem reports, corrective actions, or recalls. These reports are regarded as part of ongoing investigations.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other

problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

APPENDIX A TO SUBPART B OF PART 26— RELEVANT LEGISLATION, REGULATIONS, AND PROCEDURES.

1. For the European Community (EC) the following legislation applies to §26.42(a) of this subpart:

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036.]

a. Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices
OJ No. L 189, 20.7. 1990, p. 17. Conformity assessment procedures.

Annex 2 (with the exception of section 4)

Annex 4

Annex 5

b. Council Directive 93/42/EEC of 14 June 1993 on Medical Devices OJ No. L 169, 12.7.1993, p.1. Conformity assessment procedures.

Annex 2 (with the exception of section 4)

Annex 3

Annex 4

Annex 5

Annex 6

2. For the United States, the following legislation applies to §26.32(a):

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents may be viewed on FDA's Internet web site at "http://www.fda.gov".]

a. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*

b. The Public Health Service Act, 42 U.S.C. 201 *et seq.*

c. Regulations of the United States Food and Drug Administration found at 21 CFR, in particular, Parts 800 to 1299.

d. Medical Devices; Third Party Review of Selected Premarket Notifications; Pilot Program, 61 FR 14789-14796 (April 3, 1996).

e. Draft Guidance Document on Accredited Persons Program, 63 FR 28392 (May 22, 1998).

f. Draft Guidance for Staff, Industry and Third Parties, Third Party Programs under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA), 63 FR 36240 (July 2, 1998).

g. Guidance Document on Use of Standards, 63 FR 9561 (February 25, 1998).